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No.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

PAR PHARMACEUTICAL, INC.,

Petitioner,

vs.

MERCK & CO., INC.,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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QUESTIONS PRESENTED

1) Whether this Court should resolve a conflict between the Third Circuit and this Court as to the rule of law governing the functionality of trade dress for prescription drugs?

2) Whether the Third Circuit may continue to impose upon generic drug manufacturers a standard of contributory liability for unfair competition based upon "reasonable anticipation", where this Court held in *Inwood v. Ives* that such a standard is "watered down and incorrect"?

3) Whether a trade dress feature is non-functional as a matter of law solely because other companies can enter the market without copying, when copying provides legitimate benefits to patients and health care professionals?

4) Whether a federal court may apply state law against unfair competition to prohibit the act of copying and selling functional product features?

STATEMENT PURSUANT TO SUPREME COURT RULES 21 AND 28.1

There were no other parties to the proceeding in the court whose judgment is sought to be reviewed.

Par Pharmaceutical, Inc. has no parent, subsidiary or affiliated corporation.

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Third Circuit, dated May 29, 1985, affirming the judgment of the district court, is not officially reported and is set forth in Appendix A. The order of the Court of Appeals, dated June 25, 1985, denying petitioner's request for rehearing is set forth in Appendix B. The judgment of the Court of Appeals, entered on July 3, 1985, subsequent to the denial of the petitioner's request for rehearing, is set forth in Appendix C.

The bench opinion of the district court, dated September 5, 1984, granting respondent's request for preliminary injunctive relief, is not officially reported and is set forth in Appendix D. The order modifying the bench opinion of the district court, dated September 26, 1984, is set forth in Appendix E. The order for preliminary and final injunction, dated September 25, 1984, is set forth in Appendix F. The final judgment and order of the district court, dated September 25, 1984, is set forth in Appendix G.

JURISDICTION

The judgment of the United States Court of Appeals for the Third Circuit was entered on May 29, 1985. Petitioner's subsequent petition for rehearing was denied on June 25, 1985. The judgment of the Third Circuit was thereafter entered on July 3, 1985.

The jurisdiction of this Court is invoked under 28 U.S.C. §1254(1). The jurisdiction of the district court was based upon 28 U.S.C. §§1331 and 1338.

CONSTITUTIONAL PROVISIONS AND STATUTES INVOLVED

The constitutional provisions involved herein are Article I, §8, clause 8 and Article VI, par. 2 of the Constitution of the United States. The federal statutory provision involved herein is §43(a) of the Lanham Act, 15 U.S.C. §1125(a). The state statutory provisions involved herein are New Jersey Statutes Annotated Sections 56:4-1 and 56:8-2.

Due to the length of these provisions, they are set forth in Appendix H.

STATEMENT OF THE CASE

This petition brings before the Court the continuing controversy over the right of generic pharmaceutical manufacturers to make available their products in the appearance to which patients and health care professionals are accustomed.

Since the decision of this Court in *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844 (1982), so-called brand-name drug manufacturers have chosen the U.S. District Court for the District of New Jersey and the Third Circuit as the forum of choice for obtaining injunctive relief against use by generic manufacturers of the same size, shape and color for generic drugs as the brand-name counterparts. In these cases, the courts have either granted the injunctive relief sought, or the defendant obtained a settlement to avoid burdensome litigation.[1]

Unfortunately, the situation arising in the Third Circuit is having a nationwide, uniform effect on the pharmaceutical industry and the delivery of generic drugs to the public. Despite the passage in all fifty states and the District of Columbia of generic substitution laws, the courts below have short-circuited these laws and the *Inwood* decision on a national basis. The reason, simply, is that the pharmaceutical industry is concentrated in the state of New Jersey, including both brand name and generic houses.[2]

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[1] Other than the instant case, these include *CIBA-Geigy Corp. v. Lemmon Co., Zenith Laboratories, Inc., Danbury Pharmacal, Inc., Chelsea Laboratories, Inc., Par Pharmaceutical, Inc. and Barr Laboratories*, No. 82-670 (D.N.J.) (settled); *CIBA-Geigy Corp. v. Zenith Laboratories, Inc., Bolar Pharmaceutical Co., Inc., Danbury Pharmacal, Inc., and Chelsea Laboratories, Inc.*, No. 82-671 (D.N.J.) (Consent Judgments except as to Bolar); *CIBA-Geigy Corp. v. Bolar Pharmaceutical, Inc.*, 547 F.Supp. 1095 (D.N.J. 1982), *aff'd*, 719 F.2d 56 (3d Cir. 1983), *cert. denied*, ____ U.S. ____, 1094 S.Ct. 1444 (1984); 747 F.2d 844 (3d Cir. 1984), *cert denied*, ____ U.S. ____, 105 S.Ct. 2678 (1985) (entry of preliminary and permanent injunctive relief); *Hoffmann-LaRoche, Inc. v. Danbury Pharmacal, Inc.*, No. 83-4922 (D.N.J.) (Consent Judgment); *CIBA-Geigy Corp. v. Zenith Laboratories, Inc.*, No. 83-4928 (D.N.J.) (Consent Judgment); *Sandoz, Inc. v. Par Pharmaceutical, Inc.*, No. 84-0335 (D.N.J.) (Consent Judgment following entry of temporary restraining order); *Eli Lilly and Company v. Barr Laboratories, Inc.*, No. 85-3110 (Consent Judgment following entry of temporary restraining order).

[2] Brand-name houses include American Cyanamid, CIBA-Geigy Corp., Hoechst-Roussell Pharmaceuticals, Hoffmann-LaRoche, Johnson & Johnson, Merck, Sandoz, Schering, and Squibb. Generic companies include Ambix, Barr, Biocraft, Carnrick, Chelsea, Faraday, Heather, Lemmon, Par, Private Formulations, West-Ward, and Zenith.

Since *Inwood*, the courts in the Third Circuit have seized upon various devices to impose liability upon the generic companies. Neither traditional notions of unfair competition, nor the express standards of this Court, appear to pose a serious obstacle to these decisions.

The burden of litigation and the result-orientation in the Third Circuit have made financially impossible, and quixotic, the ability of generic companies to avail themselves of the ambit of protection for imitation afforded by *Inwood v. Ives*. This will foreclose the continuation of the traditional practice of providing generic drugs in the appearance to which patients, pharmacists, and nurses are accustomed. These rules of unfair competition being applied in the Third Circuit contravene the letter and spirit of this Court's decision in *Inwood*, and undermine the state policies encouraging generic substitution. In fact, they effectively grant a monopoly of color in perpetuity after the seventeen-year product patent monopoly has expired.

This case is particularly suited to resolution by this Court. For the first time, a district court in New Jersey has expressly found that there are legitimate advantages to imitation by a generic drug company and legitimate benefits to consumers. In applying its rule of law, the court, however, held that these advantages do not establish functionality. Such a decision makes it possible for this Court to provide meaningful guidance to the entire industry and to the lower courts, as well as to address the underlying public interest in removing artificial federal obstacles to the effectiveness of state laws of generic substitution.

Respondent Merck & Co., Inc. ("Merck") is the manufacturer of a medicine generally known as INDOCIN. INDOCIN, the brand-name of a substance known pharmaceutically as indomethacin, has been marketed for approximately twenty years as useful in the treatment of arthritis and related conditions. Its typical consumer tends to be elderly, and uses the drug on a repeated basis for the chronic disease. Traditionally, refills of INDOCIN have accounted for at least as many sales as new prescriptions for INDOCIN.

Since its initial marketing, INDOCIN has been sold with a blue and white capsule. Various markings currently appear on the blue/white capsule; the white portion of the capsule bears the word "INDOCIN" and the blue half (the cap) bears the letters "MSD" plus either the number 25 or 50. The numbers are apparently intended to show the dosage strength. At no time during the marketing of INDOCIN has the word "Merck" appeared on the capsule, and the word "INDOCIN" did not appear on the capsule until 1981.

INDOCIN, like almost every brand name drug, was subject to a patent during most of its marketing life. The patent expired in late 1981, and was soon followed by various applications to the U.S. Food and Drug Administration ("FDA") by generic manufacturers for approval to market generic indomethacin.

Following the decision in June of 1982 of this Court in *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844 (1982), and in light of other factors, including traditional industry practice, and the pattern of indomethacin use by the elderly for the chronic disease arthritis, Par Pharmaceutical, Inc. ("Par") in July of 1982 filed its application to the FDA for the marketing of indomethacin in the colors blue and white. The application included as part of the trade dress the Par logo in two places on each capsule.

The label for the container of Par's product bore the color brown, where Merck had been using blue labels, and the Par label included the Par logo prominently and conspicuously displayed at the top of the front panel. The general presentation of the Par container was dissimilar from the Merck container. In light of these facts, Merck was able to show no instance of any mistake or confusion with respect to the dispensing of generic indomethacin. Moreover, Merck presented not one instance of illegal substitution or trademark infringement concerning INDOCIN.

Under the relevant standards in *Inwood* of functionality, Par adduced uncontradicted proof of four areas in which trade dress serves a purpose other than identification of source. On these

points, there was unanimity among the experts. These experts included a physician ostensibly appearing for Merck and the only non-employee offered by Merck; the Director of Nursing at the Teaneck, New Jersey Nursing Home; the Director of Nursing at the Troy Hills, New Jersey Nursing Home; and a pharmacist with over twenty years of experience operating retail drug stores.

The experts testified that the trade dress of a branded prescription drug:

1) Identifies for the patient at the time of dispensing the type of medication in terms of its therapeutic effect. These experts testified that patients, when presented with a generic substitute in an unfamiliar color, become confused by the change in color, believing that the wrong medication had been dispensed;

2) Assists patients, particularly the elderly, to adhere to a schedule of ingestion when such patients are taking multiple medications. Many such patients co-mingle their medications in a single container and are able to distinguish among the medications because of their familiarity with the physical appearance of those medications;

3) Assists health care professionals in dispensing the proper medication;[3] and

4) Assists health care professionals to identify medication in emergency situations.

The evidence also showed that Merck investigated for over twenty years the functionality of color and has during that period incorporated the conclusions of its investigation into its color selection process. For example, internal Merck documents

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[3] In his concurring opinion in *Inwood*, Mr. Justice White observed that these advantages establish the functionality of trade dress at every stage of distribution. See discussion at page 11, *infra*.

from the early 1960's, which documents were routed to the individuals who chose the colors for INDOCIN, identified blue as a "cool" and "sedat[ing]" color. INDOCIN, coincidence or not, is a blue-colored drug intended to have a sedating-type effect on arthritic pain.

More recently, Merck's internal investigations have taken a new and more significant direction. In 1981, Merck commenced an investigation at the top level of management into the effect of physical appearance on substitution rates. Merck adopted as the premise for further investigation the fact that patients would be "upset if an unfamiliar pill was substituted for a familiar one."

As part of its further investigation, Merck reviewed the substitution rates of over sixty types of drugs which were available from multiple sources, *i.e.*, brand name manufacturer and generic companies. Merck concluded that the unavailability of imitative generics caused an average decrease in the generic market of over 40%. Merck further recommended as part of a "strategy to minimize the impact of generic competition ..." that it should try to create appearance distinctions between its products and generic competitors, based upon the conclusions of the study.[4]

On the face of the record below, the district court found that Par had "established" that:

1) imitation of trade dress provides a means of reassuring patients that they are receiving the right medication;

2) that imitation of trade dress assists patients who commingle their medications to adhere to their schedule of ingestion; and

3) that imitative trade dress assists health care professionals to dispense the correct medications. A-18[5]

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[4] It may be noted that this quality of evidence on the functionality of prescription drug colors was not even available in *Inwood*.

[5] These findings matched three of the four findings of the district court in *Inwood*.

The handling of this overwhelming evidence in the lower court raises serious questions of law. Under the rule of law expressed in *Inwood*, these findings established functionality. Par should have at that point prevailed. However, the district court, as affirmed by the Third District, applied a different rule; a rule contradictory to *Inwood*. According to the district court, the established, legitimate advantages of using blue and white for Par's capsules did not establish functionality because "[a]ny functional uses of the blue and white color scheme were not sufficiently substantial to preclude this competition from entering the market place." A-19. According to the district court, "I do not believe that *Inwood v. Ives* constitutes a ruling on functionality under either Section 32 or Section 43(a)..." A-20.

The district court also held that Par was liable under New Jersey state law because it reasonably anticipated passing off by others. The court referred to no instance of passing off, and no elements of the offense than "reasonable anticipation" of passing off.

On appeal, the Third Circuit affirmed. It affirmed the finding of non-functionality. It also explicitly affirmed the "reasonable anticipation" theory of liability:

> "Merck need only prove that 'a drug manufacturer ... put a product in the hands of a pharmacist in a form in which the manufacturer can reasonably anticipate that it may be passed off as another product even if the manufacturer does nothing else to encourage passing off.' " A-4.

Par petitioned the Third Circuit for rehearing. In its petition, Par argued that the district court had applied a rule of law contrary to *Inwood*. Par specifically argued that the findings of legitimate advantages for imitation compelled a finding of functionality under the rule of *Inwood*. Par further expressed its belief that the majority opinion of the Court in *Inwood* as well as Mr. Justice White's opinion had put to rest the "reasonable anticipation" theory of liability, and that the Third

Circuit's use of such a standard was improper. This request was denied.[6]

In light of the rules in the Third Circuit governing the appearance of generic drugs, Par shares the view of a recent commentator that the pattern of these decisions deserves intervention by this Court:

> "Manufacturers of branded prescription drugs appear to have staked out district courts in the 3d U.S. Circuit Court of Appeals as the courts of choice for lawsuits challenging the sale of 'look-alike' generic drugs. In several recent cases, the 3d Circuit has consistently sided with the brand manufacturers."
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> * * *
>
> "One can only hope that the Supreme Court soon will again take an interest in these issues and articulate standards that will lend some predictability to this area of the law." Plevan and Siroky, *The 3d Circuit Gets a Dose of Suits Filed Against 'Look-Alike' Drugs*, Nat. Law J. Aug. 12, 1985 at 22.

REASONS FOR GRANTING THE WRIT

I. CERTIORARI SHOULD BE GRANTED TO RESOLVE THE CONFLICT BETWEEN THE STANDARD OF FUNCTIONALITY IN *INWOOD v. IVES* AND THE NEW RULE OF FUNCTIONALITY IN THE THIRD CIRCUIT

In the courts below, there were factual findings almost identical to the findings in *Inwood*. The district court found that Par's use of blue and white capsules for indomethacin had three

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[6] The petition for rehearing also requested the Third Circuit to correct three errors in its factual references to the record. The order denying the petition made no reference to these proposed corrections of the record references. A-6.

legitimate advantages – (1) to help assure patients that they are getting the correct medication; (2) to assist patients who commingle their medications to identify which medicine to take at the proper time; and (3) to assist health care professionals in dispensing the correct medication.

Under *Inwood*, there should have been a finding of functionality. In *Inwood*, the district court likewise made these three findings [7] and this Court held that it was not clearly erroneous for the district court to hold that these advantages constituted functionality.[8]

The court below, however, applied a different rule. It announced a new rule that a trade feature is not functional, as a matter of law, if other companies were able to enter the market without imitating that feature, even if there are legitimate reasons to imitate.

Par respectfully believes that such a new definition of functionality is directly contrary to *Inwood* and an undesirable proposition of the law of unfair competition.

In *Inwood*, the brand-name company made exactly the same argument. There, the evidence in the record showed that other companies had entered the market in that product without using the familiar colors of the CYCLOSPASMOL product. If, in fact, functionality includes as part of its definition an element of proof on the inability of others to compete without imitating, the district court in *Inwood* would have been wrong. There would have been no functionality. This Court, however, held that the district court was not clearly erroneous. In effect, this Court rejected the "barrier to market entry" definition of functionality.

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[7] The district court here found that he was not "persuaded" that imitation "materially assists" the doctor in emergency identification. A-18.

[8] On remand in *Inwood*, the Second Circuit affirmed the district court's holding that the imitation of Ives' product did not violate Section 43(a) of the Lanham Act, 15 U.S.C. 1125(a).

Par further believes that the ad hoc and incorrect definition of functionality below underscores the need for this Court's intervention. In the various cases involving this overall controversy, the lower courts have reviewed basically the same evidence of functionality and established different results. It is really no longer disputed, even by the brand-name industry, that patients and health care professionals identify the type of medication, rather than its source, based upon its size, shape and color.

The underlying controversy is whether such advantages establish "functionality." The evidence in these cases rarely, if ever, arises from some special characteristics of the particular drug at issue. Rather, the fact of legitimate advantages for trade dress imitation applies across the spectrum of prescription products.

Mr. Justice White in his concurring opinion in *Inwood* quoted a leading commentator on this very point. He wrote:

> "The reality is that for every link in the distributive chain (from producer to ultimate consumer) the color and shape of drugs dispensed by prescription do perform a function. For each of them, color or shape may be a convenient shorthand code by which to identify the drug and its milligram dosage so that mistakes can be avoided in the interests of pharmaceutical precaution and patient safety. For the patient-user, of course, the constancy of color and shape may be as psychologically reassuring and therefore as medically beneficial as the drug itself; in addition; they also serve to identify the drug for his ingestion....
>
> "(I)f the generic producer is constrained by §43(a), the trademark law, or the law of unfair competition to adopt a substantially different color... the therapeutic value of his generic drug might be seriously impaired and confusion at the pharmacist level could be compounded beyond redemption. 3R Callmann, Unfair Competition, Trademarks and Monopolies §82.1 (m), pp 217, 213 (Supp 1981)." *Inwood*, 456 U.S. at 862 n.3

Another observer has specifically noted that this issue of "functionality" presents sufficient legal questions for this Court to resolve:

> "At first blush, the issues of functionality and secondary meaning appear to be too fact-bound to merit Supreme Court attention. The facts giving rise to these and other look-alike drug cases, however, are so similar and have arisen so frequently that there should be no impediment to the Supreme Court resolving many of the dispositive issues as a matter of law. For example, regarding proof of functionality, it was conceded in both *Ives* and *Bolar* that the plaintiffs' initial choice of colors for its products was arbitrary and fanciful. Yet, after the drugs had been on the market for several years, the colors have acquired certain significance to customers. Whether colors could become functional after a period of time is a question addressed in both cases, yet the courts reached opposite conclusions on the basis of identical indicia of functionality, such as the anxiety of elderly patients receiving unfamiliar drugs." Plevan & Siroky, National Law Journal, *supra*.[9]

The large and still-growing body of evidence about the market of prescription drugs continues to show that, absent special circumstances, the use of familiar product appearances by generic companies does not mislead the public, but rather improves patient compliance and assists in the safe dispensing and ingestion of such drugs.

In the light of the findings by the district court of legitimate reasons for Par to use the same size, shape and color capsules as Merck, this case presents an appropriate opportunity for this

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[9] Par further believes that the Third Circuit standard of secondary meaning in these cases is wrong. In the unique prescription drug area, advertising is directed at professionals, not patients. Thus advertising is a poor indicia of consumer belief. Likewise, it is paradoxical to regard the act of imitation as an indicia of secondary meaning where there are legitimate reasons to imitate.

Court to reaffirm the vitality of *Inwood*. In so doing, the Court can correct the standard of law now applied in the Third Circuit and remove a major barrier to effective delivery to the public of low-priced generic drugs. Par believes that certain lower courts should not be free to ignore *Inwood* simply because they disagree with its outcome.

II. CERTIORARI SHOULD BE GRANTED TO DETERMINE WHETHER THE STANDARD OF CONTRIBUTORY LIABILITY BASED UPON "REASONABLE ANTICIPATION" CAN SURVIVE AFTER *INWOOD v. IVES*

In *Inwood*, the source of greatest controversy among the parties was whether "reasonable anticipation" alone could provide a sufficient basis for imposing liability upon a manufacturer. The Court rejected the rule of "reasonable anticipation". The majority described the "reasonable anticipation" theory as " 'watered-down' and incorrect." 456 U.S. at 854 n.13. In his concurring opinion, Mr. Justice White vigorously discussed and criticized the "reasonable anticipation" standard. 456 U.S. at 861-62.

The Third Circuit, however, has continued to expressly apply this standard. In the decision below, the Third Circuit held that:

> "For its New Jersey passing off claim, Merck need only prove that 'a drug manufacturer ... put a product in the hands of a pharmacist in a form in which the manufacturer can reasonably anticipate that it may be passed off as another product even if the manufacturer does nothing else to encourage passing off. *Ciba-Geigy*, 747 F.2d 844, 852 (3d Cir. 1984) (*citing SK&F*, 625 F.2d at 1062)." A-4.

One may note at the outset that no such standard actually exists in any New Jersey statute or case law. As stated succintly by Judge Giles in dissent in another post-*Inwood* decision of the Third Circuit:

"Nothing in the 'general tenants' of New Jersey unfair competition law, as articulated by the *Merrell* court, tends to prove that New Jersey would adopt the reasonable anticipation standard over the test of intentional inducement. Indeed, the SK&F court's acknowledgment that New Jersey follows sections 711 and 713 of the Restatement (First) of Torts would indicate the exact opposite. The only insight provided by New Jersey courts is found in dicta in the *French American Reeds* case. The Superior Court of New Jersey noted that the action did not present questions of passing off or 'fraudulent marketing,' citing the Restatement (First) of Torts §711(1938). Quoting plaintiff, the court stated that the claim did 'not involve any element of actual intent or any attempt on respondents' part to see their goods as those of appellant.' *French American Reeds*, 20 N.J. Super. at 329, 90 A.2d at 52. If reasonable anticipation were the standard in New Jersey, the plaintiff in *French American Reeds* might not have limited the case to claims of unprivileged imitation.

"Discounting the so-called 'general tenants' of unfair competition, the *Merrell* decision, upon which the SK&F court relied, is based upon an analogy to federal law. This analogy is not longer justified in the wake of Ives. Assuming the reasonable anticipation standard has been overruled as a matter of federal law, it follows that it cannot be viable under New Jersey law in the absence of any endorsement of that standard by the court of New Jersey." [11] *CIBA-Geigy v. Bolar*, 747 F.2d at 863.

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[11] Given the continued prohibition against imitation under Section 43(a) where there is no act of inducement of passing off by the manufacturer, the Third Circuit is also implicitly using a "reasonable anticipation standard" under federal law.

Assuming, however, that such a rule exists, it cannot stand. The intolerable effect of the rule is to completely prohibit trade dress imitation under the rubric of New Jersey Law, because anyone in business can expect some unknown bad actors to engage in passing off. As Judge Wyzanski wrote:

> "Any man of common sense knows that in any line of business...there are some unscrupulous persons who, when it is to their financial advantage to do so, will palm off on customers a different product from the one they ordered." *Coca-Cola Co. v. Snow Crest Beverages*, 64 F. Supp. 980, 989 (D. Mass. 1946), *aff'd*, 162 F.2d 280 (1st Cir.), *cert denied*, 332 U.S. 809 (1947).

In *Sears-Compco*, this Court described the circumstances under which state law could not impose liability. It held that a state could not enjoin imitation itself, absent a patent, but only require disclosure of the source of the product. What *Sears-Compco* said a state could not do is exactly what the state law applied below does:

> "As we have said in Sears, while the federal patent laws prevent a State from prohibiting the copying and selling of unpatented articles, they do not stand in the way of state law, statutory or decisional, which requires those who make and sell copies to take precautions to identify their products as their own. A State of course has power to impose liability upon those who, knowing that the public is relying upon an original manufacturer's reputation for quality and integrity, deceive the public by palming off their copies as the original. That an article copied from an unpatented article could be made in some other way, that the design is 'nonfunctional' and not essential to the use of either article, that the configuration of the article copied may have a 'secondary meaning' which identifies the maker to the trade, or that there may be 'confusion' among purchasers as to which article

> is which or as to who is the maker, may be relevant evidence in applying a State's law requiring such precautions as labeling, however, and *regardless of the copier's motives, neither these facts nor any others can furnish a basis for imposing liability for or prohibiting the actual acts of copying and selling, Cf. Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111, 120, 59 S.Ct. 109, 114, 83 L.Ed. 73 (1938). And of course a State cannot hold a copier accountable in damages for failure to label or otherwise to identify his goods unless his failure is in violation of valid state statutory or decisional law requiring the copier to label or take other precautions to prevent confusion of customers as to the source of the goods." *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S., 234, 238-39 (1964). [emphasis added] *See also Sears Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 232 (1964).[12]

As a matter of policy, Par also believes that the supposed view of New Jersey law is unwise. The pharmaceutical industry is national, if not international, in scope. Patient care is a national issue. Hence, the delivery of prescription drugs involves a national system. In this regard, in a very brief period every single state has passed generic substitution laws which are designed to deliver to the public generic drugs at reasonable prices below the monopoly price structure charged by brand-name companies during and after patent life.

The supposed rule of New Jersey law creates the unusual situation where what is lawful imitation elsewhere is unlawful in New Jersey. Such a rule would compel generic drug manufacturers to refrain from imitation on all its products, and thereby

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[12] There is no evidence that pharmacists are, as a class, less honest than any other group of people. Thus, it is particularly undesirable to permit a ban on copying in the prescription drug field. where there are legitimate reasons to imitiate.

forego delivering the acknowledged benefits of imitation to every patient and health care professional in the country, solely because of New Jersey state law; or to manufacture a separate product for sale in New Jersey. The costs of maintaining separate production, inventory and distribution control systems under the latter alternative would be so expensive as to jeopardize the very purpose of generic drugs in the health care system.[13]

The rule of "reasonable anticipation" as applied by the Third Circuit would effectively end the ability of generic pharmaceutical companies to provide products in the size, shape, and color to which patients and professionals are accustomed. This consequence, if permitted by the Court to continue, would interfere with the policy of all fifty states and the District of Columbia. Par respectfully believes that a federal court such as the Third Circuit may not properly invoke a non-existent doctrine of state law and apply such a doctrine in order to prohibit that which is encouraged by all state laws, and permitted by federal law.

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[13] Par, like many other generic manufacturers, would not even be guaranteed this choice by the Third Circuit, since it is located in New Jersey.

CONCLUSION

It is respectfully requested that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Third Circuit.

Respectfully submitted,

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APPENDIX

APPENDIX A

OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT, *MERCK & CO., INC. v. PAR PHARMACEUTICAL, INC.*, NO. 84-5689 (3d Cir. May 29, 1985)

United States Court of Appeals

for the

Third Circuit

No. 84-5689

MERCK & CO., INC., a New Jersey Corporation,

Appellee,

vs.

PAR PHARMACEUTICAL, INC.,
a New Jersey Corporation,

Appellant.

Appeal From the United States District Court
For the District of New Jersey - Newark
D.C. Civil No. 84-1559
District Judge: Honorable Dickinson R. Debevoise

Argued May 16, 1985

Before: HUNTER, SLOVITER, *Circuit Judges*, and MUIR,* *District Judge*

Opinion filed May 29, 1985

*Honorable Malcolm Muir, United States District Judge for the Middle District of Pennsylvania, sitting by designation

MEMORANDUM OPINION OF THE COURT

HUNTER, *Circuit Judge:*

1. Appellant Par Pharmaceutical, Inc. ("Par") appeals the judgment of the District Court for the District of New Jersey permanently enjoining them from marketing a drug called indomethacin in a trade dress virtually identical to that of Merck & Co., Inc. ("Merck").

2. Appellee Merck is a pharmaceutical company in New Jersey well known for its research, development, manufacture and distribution of drugs. The Merck laboratories discovered indomethacin in 1959, a drug which is used as an anti-inflammatory in treating the symptoms of ailments such as arthritis, ankylosing spondylitis, gouty arthritis, bursitis and tendonitis. Merck has marketed indomethacin under the trade name of "Indocin" since 1965 in a hard, opaque, blue and white capsule and has been highly successful. Merck held a patent on indomethacin until it expired on December 15, 1981. At that time the FDA approved four generic firms in the United States to market indomethacin, but none of these companies chose to dress the capsules in the Merck blue and white. The generic firms began to market indomethacin in 1984 at prices 18 to 20 percent below that of Merck. By mid-July 1984 more than 50 percent of all indomethacin prescriptions were being filled with generic indomethacin.

3. Par, another generic drug manufacturer, submitted a New Drug Application to the FDA in 1982, seeking approval for their version of indomethacin. In their application, Par specified that they planned to put the drug in blue and white capsules almost identical to those of Merck, with their name, "PAR" in black letters. On its blue and white capsules, Merck has printed "MSD" in letters of the same size and shape.

4. Par's President, Perry Levine, testified in his deposition that he decided on the blue and white configuration for the capsules, so strikingly similar to the trade dress of Indocin, because he felt that Par's drug would be more easily accepted in the

marketplace if it looked like Indocin. The district court found, as an additional reason for Par's selection of the blue and white capsules the effort "to obtain a competitive advantage over competing generic manufacturers who had selected other colors."

5. When Merck discovered that Par had a substantial inventory of the product ready to be shipped when FDA clearance was obtained, and intended to market its version of indomethacin in the same trade dress as Merck, it brought an immediate action for a preliminary injunction. Merck claims it is entitled to an injunction under section 43(a) of the Lanham Act, 15 U.S.C. §1125(a) (1982) and New Jersey statutory and common law proscriptions on "passing off" and "unprivileged imitation." After some initial discovery procedures, Merck learned that Par had indeed obtained FDA approval, had in fact shipped approximately nine million blue and white indomethacin capsules and had outstanding unfilled orders for many more. Merck then applied for a temporary restraining order prohibiting Par from shipping or distributing indomethacin in Merck's trade dress. The district court granted Merck's application on August 13, 1984. On September 4, 1984, the district court entered a bench opinion with findings of fact and conclusions of law ruling that Merck had fulfilled the requirements for a preliminary injunction. Par and Merck then submitted documents to the district court in order to allow it to convert the prelimary injunction into a permanent injunction, appropriate to effect a final, appealable order. The district court entered a final judgment on September 25, 1984, finding that Merck had established its claims of passing off and unprivileged imitation under New Jersey law and its section 43(a) claim under the Lanham Act. The court adopted its findings and conclusions as final based upon the record before the court at the time of the decision on the preliminary injunction. It entered a permanent injunction prohibiting Par from selling indomethacin in blue and white capsules so similar to those of Merck.

6. The district court ruled in favor of Merck based primarily on *SK&F, Co. v. Premo Pharmaceutical Lab.*, 625 F.2d 1055

(3d Cir. 1980), a case similar to this one. There, this court upheld a district court preliminary injunction which prohibited a generic drug manufacturer from marketing a drug containing an oral diuretic in hard gelatin capsules having the same maroon and white color combination as the capsules used in marketing the plaintiff's similar product. As here, the plaintiff in *SK&F*, alleged violations of the New Jersey passing off and unprivileged imitation statutes and the Lanham Act, section 43(a). But what more strikingly compels us to uphold the district court's injunction is that after the district court in the case before us here had issued its opinion, our court decided another trade dress case, *Ciba-Geigy Corp. v. Bolar Pharmaceutical Co., Inc.*, 747 F.2d 844 (3d Cir. 1984). In *Ciba-Geigy*, as here, the district court transformed a preliminary injunction into a permanent injunction. We upheld the permanent injunction against a generic drug manufacturer, prohibiting it from distributing a drug in the same trade dress as that of the plaintiff pharmaceutical company.

7. Under both *Ciba-Geigy* and *SK&F*, this court set out the standards for establishing a claim under the New Jersey passing off and unprivileged imitation laws, as well as section 43(a) of the Lanham Act. For its New Jersey passing off claim, Merck need only prove that "a drug manufacturer ... put a product in the hands of a pharmacist in a form in which the manufacturer can reasonably anticipate that it may be passed off as another product even if the manufacturer does nothing else to encourage passing off." *Ciba-Geigy*, 747 F.2d 844, 852 (3d Cir. 1984) (*citing SK&F*, 625 F.2d at 1062). The district court here found that Merck had succeeded in proving that Par could reasonably anticipate that pharmacists would illegally substitute its drug for that of Merck. We cannot say that the district court's finding was clearly erroneous.

8. To establish a claim for unprivileged imitation under New Jersey law, Merck must show "(a) that an imitated feature of its product is non-functional, (2) that the imitation is likely to cause confusion as to the product's origin, and (3) that the product has acquired secondary meaning." *Ciba-Geigy Corp. v.*

Bolar Pharmaceutical Co., 747 F.2d 844, 850 (3d Cir. 1984).[1] The district court in the case before us, faced almost identical contentions of functionality and found, as a matter of fact,[2] that the blue and white trade dress was non-functional. It also found that the imitation was likely to cause confusion and that Merck's blue and white capsules had acquired secondary meaning denoting a common source. We cannot say that any one of these findings by the district court was clearly erroneous.

9. The decision in *Ciba-Geigy* controls our disposition of Merck's federal cause of action under the Lanham Act as well. "To establish unprivileged imitation under the Act, a plaintiff must prove the non-functionality of the imitated feature and prove secondary meaning of the imitated feature. These proofs are essentially the same as those required for unprivileged imitation under New Jersey law." *Ciba-Geigy*, 747 F.2d at 854. The district court's findings here as to functionality and secondary meaning are not clearly erroneous. Therefore, as we held in *Ciba-Geigy*, those findings establish the validity of the federal claim as well.

10. Accordingly, the judgment of the district court will be affirmed.

TO THE CLERK

Please file the foregoing opinion.

JAMES HUNTER, III, *Circuit Judge*

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[1] The Supreme Court in *Inwood Laboratories v. Ives Laboratories*, 456 U.S. 844, 850-51 (1982), defined both functionality and secondary meaning. The Court said there that "a product feature is functional if it is essential to the use or purpose of the article or if it affects the cost or quality of the article." *Id.* at 850. "To establish secondary meaning, a manufacturer must show that, in the minds of the public, the primary significance of the product feature or term is to identify the source of the product rather than the product itself." *Id.* at 851.

[2] *See Ciba-Geigy*, 747 F.2d at 850 (court's finding on functionality is finding of fact).

APPENDIX B

ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT, *MERCK & CO., INC. v. PAR PHARMACEUTICAL, INC.*, NO. 84-5689 (3d Cir. June 25, 1985)

United States Court of Appeals
for the
Third Circuit

No. 84-5689

MERCK & CO., INC., a New Jersey Corporation,
Appellee,

vs.

PAR PHARMACEUTICAL, INC., a New Jersey Corporation,
Appellant.

SUR PETITION FOR REHEARING

Present: ALDISERT, *Chief Judge*, SEITZ, GIBBONS, HUNTER, WEIS, GARTH, SLOVITER, BECKER, STAPLETON and MANSMANN, *Circuit Judges*

The petition for rehearing filed by

APPELLANT

in the above entitled case having been submitted to the judges who participated in the decision of this court and to all the other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the circuit judges of the circuit in regular active service not having voted for rehearing by the court in banc, the petition for rehearing is denied.

By the Court,

s/James Hunter
Judge

Dated: June 25, 1985

APPENDIX C

JUDGMENT OF THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT, *MERCK & CO., INC. V. PAR PHARMACEUTICAL, INC.*, No. 84-5689 (3d Cir. July 3, 1985)

United States Court of Appeals

for the

Third Circuit

No. 84-5689

MERCK & CO., INC., a New Jersey Corporation

Appellee

vs.

PAR PHARMACEUTICAL, INC., a New Jersey Corporation

Appellant

Appeal From the United States District Court
For the District of New Jersey - Newark
D.C. Civil No. 84-1559
District Judge: Honorable Dickinson R. Debevoise

Before: HUNTER, SLOVITER, *Circuit Judges*, and MUIR,* *District Judge*

JUDGMENT

This cause came to be heard on the record from the United States District Court for the District of New Jersey and was argued May 16, 1985.

* Honorable Malcolm Muir, United States District Judge for the Middle District of Pennsylvania, sitting by designation.

On consideration whereof, it is now ordered and adjudged by this Court that the order of the District Court entered September 25, 1984 be, and the same is hereby, affirmed.

Costs taxed against appellant.

ATTEST:

Clerk

May 29, 1985

Certified as a true copy and issued in lieu
of a formal mandate on July 3, 1985.

Test:

Chief Deputy Clerk, United States Court of Appeals
for the Third Circuit.

APPENDIX D

OPINION OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW JERSEY, *MERCK & COMPANY, INC. v. PAR PHARMACEUTICAL, INC.*, NO. 84-1559 (D.N.J. Sept. 5, 1984)

United States District Court

for the

District of New Jersey

Civil Action No. 84-1559

MERCK & COMPANY, INC., a New Jersey corporation,

Plaintiff,

vs.

PAR PHARMACEUTICAL, INC., a New Jersey corporation,

Defendant.

TRANSCRIPT OF PROCEEDINGS

Newark, New Jersey
September 5, 1984

BEFORE:

HONORABLE DICKINSON R. DEBEVOISE, U.S.D.J.

Appearances:

SHANLEY & FISHER, ESQS.
BY: RONALD GOULD, ESQ.
Attorneys for the Plaintiff

LAWRENCE H. ROTH, ESQ. (NY)
Attorney for the Defendant

THE COURT: I'm going to put an opinion on the record reserving the opportunity to go over it and make any corrections after it has been initially typed. Then it can be distributed to the parties and filed with the Court.

Plaintiff, Merck & Co., Inc., instituted this action against defendant, Par Pharmaceutical, Inc., charging false designation of origin and false description or representation of goods in violation of Section 43(a) of the Lanham Act, 15 U.S.C. Section 1125(a). In addition, Merck charges unfair competition in violation of New Jersey's statutory and common law.

Since 1965 Merck has manufactured and distributed the prescription drug indomethacin under its registered trademark INDOCIN. Merck's patent on the drug expired and a number of companies, as they are entitled to do, commenced selling the generic drug. Par is one of these companies. In this suit Merck challenges the color and shape of the indomethacin pills which Par intends to distribute. When Merck learned that distribution of the pills was imminent it sought a temporary restraining order and preliminary injunction. After a hearing I granted the temporary restraining order and scheduled a hearing on the application for preliminary injunction. Extensive affidavits, depositions and exhibits have been filed.

A hearing has been held at which additional argument was given. Neither side sought to call witnesses. This constitutes my findings of fact and conclusions of law.

THE FACTS

Merck is a New Jersey corporation having its principal place of business in this state. It is well known for its work in research, development, manufacture and distribution of pharmaceutical products. Indomethacin was discovered in the Merck laboratories in 1959 and thereafter was approved by the United States Food & Drug Administration for treating certain ailments. It is a prescription pharmaceutical dispensed by retail pharmacists only upon the prescription of a physician. Merck sells it under its trademark Indocin.

Since 1965, Merck has manufactured and distributed the prescription drug indomethacin in capsule form for oral administration to human patients for use as an anti-inflammatory agent. Indomethacin in is a highly successful therapeutic agent in the field of human rheumatoid arthritis, ankylosing spondylitis, gouty arthritis, osteoarthritis, bursitis and/or tendonitis.

Indomethacin has been prepared for sale to the ultimate consumer (the patient for whom it is prescribed) in hard gelatin capsules. The capsules bear the following logos:

25 milligram capsule: MSD

25

50 milligram capsule: MSD

50

Both the 25 milligram capsule and the 50 milligram capsule are opaque, blue and white, and in some cases the printing thereon is vertical, and in some instances, horizontal. Commencing in 1981 the trademark INDOCIN has also been printed on the capsules. The capsules are standard No. 1 and No. 3 capsules. The 25 milligram indomethacin capsule was introduced on the market on June 21, 1965 and the 50 milligram capsule was introduced April 26, 1968. Since 1965 when Merck introduced indomethacin until Par introduced its product, there had been no other product containing indomethacin as an active ingredient marketed in the United States as a prescription medication in the same combinations of colors, sizes and shapes as Merck's indomethacin.

Annual sales of INDOCIN increased from $11,537,000 in 1965 to $98,201,000 in 1983. Patients for whom indomethacin was prescribed were likely to use it over extended periods of time. Merck has engaged in extensive nationwide advertising and promotion of its indomethacin product. Total expenditures for these

purposes for the years 1965 through 1983 have exceeded $75,000,000. A major portion of its material is directed to physicians and druggists. Some is carried in journals read both by professionals and laymen. Some is contained in books on prescription drugs prepared for laymen. The colors, sizes and shapes of Merck's indomethacin capsules have been featured in its advertising and promotion and serve to identify both the product and the source, namely, Merck.

On the basis of the deposition testimony of Douglas M. Durand, Merck's product manager for Indocin, Par attacked Merck's advertising expenditure figures. While there appears to be merit to Par's observations, the advertising expenses were nevertheless very great.

The product patent on indomethacin expired on December 15, 1981. Thereafter four generic firms received FDA approval to market indomethacin in the United States. These firms are Mylan Pharmaceuticals, Inc., which uses green capsules, Lederle Laboratories, which uses pink and white capsules, Chelsea Laboratories, Inc., which uses orange capsules, and Zenith Laboratories, Inc., which uses white capsules.

In the early summer of 1984 the prices of generic indomethacin sold by these firms were 18 percent to 28 percent below the price of Merck's indomethacin. As more firms commence producing the generic drug, the differential is likely to increase. Although the generic products were first approved in late April 1984, by mid-July 1984 more than 50 percent of new prescriptions for indomethacin were being filled with generic products other than Merck's INDOCIN.

Par is a generic drug manufacturer. In July 1982 Par submitted a New Drug Application to the United States Food & Drug Administration, seeking approval for the marketing of its generic version of indomethacin.

Par specified a blue and white color configuration for its product and included its name "Par" in black letters on its capsule, just as Merck included the identifying letters "MSD" on

its capsules. Par's President, Perry Levine, states he was responsible for selecting the blue and white color configuration. He gives the following rational for his decision to select a trade dress which is strikingly close to the Indocin trade dress: "In order for generic drug products to be accepted in the marketplace by patients, we believe the similarity in appearance insofar as size and shape and color are concerned is an important functional attribute of a medicinal product such as the one involved in this case. If a generic product was *lawfully* dispensed after a patient had been taking a brand name product, the discovery of a different color would ususally be made by the patient at home. I believe, and my belief is supported by the general medical community, that such a patient would suffer much anxiety and confusion if the accustomed medicine were dispensed in a different color, even though they otherwise knew they were supposed to be getting a generic version in place of a brand name product... Of further importance is the fact this the capsule colors assist patients in identifying the appropriate medicine to take at the appropriate time."

I find an additional reason for Par's color selection is to obtain a competitive advantage over competing generic manufacturers of generic indomethacin who selected other colors. It is not without significance that one of Par's potential customers solicited orders for the Par product by describing it in banner letters as "INDOCIN GENERIC LOOK-ALIKE."

In its application for injunctive relief Merck urges that the existence of a generic product which looks like its INDOCIN is an invitation to less than scrupulous or careless pharmacists to substitute the generic product for INDOCIN, when selling to customers, thereby reaping a handsome profit. Par says that it has no interest or intent to promote such illegal acts and has taken steps to prevent such occurences. Its bottles containing the capsules are round, while Merck's are rectangular. The color and layout of its labels differ from Merck's; its name is prominently displayed on the bottles and capsules; the bottles sold to pharmacists include cautionary language on an adhesive sticker attached to the top of the bottle:

> "Notice: This product may be substituted for Indocin only when authorized by law. When dispensing label this product only as INDOMETHACIN."

Par undertakes to stop selling to any pharmacist or other person engaging in any illegal acts involving its product.

On August 6th, 1984 Par received FDA approval to market its indomethacin and on August 7th shipped 9,000,000 capsules. At the time I entered the temporary restraining order there were outstanding unfilled orders for capsules.

CONCLUSIONS OF LAW

The Court has federal question and pendent jurisdiction of this case.

The prerequisites for preliminary injunctive relief in this circuit are (1) a reasonable probability of ultimate success on the merits and (2) irreparable injury during the pendency of the action if the relief is not granted to prevent a change in the status quo. *SK&F Co. against Premo Pharmaceutical Laboratories, Inc.*, 481 F. Supp. 1184 (D.N.J. 1979) *aff'd*, 625 F.2d 1055 (3d. Cir. 1980). Where relevant, the Court should take into account (3) the possibility of harm to other interested parties harmed by the relief and (4) the public interest. *Delaware River Port Authority v. Transamerican Trail Transport, Inc.*, 501 F.2d 917 (3d Cir. 1974).

1. *The Merits*. The case is governed by the Third Circuit opinion in *SK&F Co. v. Premo Pharmaceutical Laboratories, supra*. See also *Ciba-Geigy Corp. v. Bolar Pharmaceutical, Inc.*, 547 F. Supp. 1085 (D.N.J. 1982) *aff'd*, 719 F. Supp. 756 (3d. Cir. 1983), *cert. denied*, 104 S. Ct. 1444 (1984). In *SK&F, supra*, the Third Circuit affirmed the District Court's preliminary injunction order preventing the defendant Premo from marketing a diuretic/hypertensive drug in capsules having the same combination of colors as plaintiff's DYAZIDE product which contained the same drug. The brand name product in the *SK&F* case was introduced by SK&F in 1965 after a long

period of research and development. It was marketed as a powder containing a maroon and white capsule with the brand DYAZIDE and the logo SK&F printed on both the white half and the maroon half of the capsule. SK&F had expended large amounts of money promoting its DYAZIDE product through a network of detail men calling on doctors, hospitals and pharmacies, and also advertised in journals likely to reach the medical profession. Doctors had prescribed DYAZIDE therapy for over 20 million patients, with average therapy extending over the course of the months or years. During this time each patient consumed hundreds of DYAZIDE capsules so as to have noted the arbitrary and distinctive appearance of those capsules.

Premo, the defendant in *SK&F*, was a manufacturer of generic pharmaceuticals. It began to market the generic substitute for DYAZIDE in capsules which utilized the same blue and white color schemes used by SK&F for many years. The Court of Appeals affirmed the District Court's finding that defendant was guilty of two types of unfair competition under New Jersey law: passing off one's goods or services as those of another, and unprivileged imitation.

With respect to "passing off," the court cited an earlier case which specifically held it to be

> actionable conduct under New Jersey law for a drug manufacturer to put a product in the hands of a pharmacist in a form which the manufacturer can reasonably anticipate that it may be passed off as another product even if the manufacturer does nothing else to encourage passing off.

SK&F, 625 F.2d at 1062 (citing, *inter alia*, *Merrel-National Laboratories, Inc. v. Zenith Laboratories, Inc.*, 194 U.S.P.Q. 157, 159-60. (D.N.J. 1977), *aff'd*, 579 F.2d. 786. (3d Cir. 1978).

The Third Circuit affirmed the District Court's conclusion that SK&F would be likely to succeed at a final hearing on this issue stating:

> As to passing off, it is undisputed that the maroon and white color scheme of a virtually identical capsule container was adopted by Premo with the intention of associating, its product in the mind of users, physicians and pharmacists, with DYAZIDE. It is nowhere suggested that Premo was unaware of the practice by some unscrupulous pharmacists of substituting less expensive generic drugs for the brand name drugs prescribed without informing their customers and without passing along the benefit of the lower price. It was reasonable for the district court to conclude that Premo's use of a practically identical trade dress would facilitate such passing off.

625 F.2d. at 1063.

With respect to the tort of unprivileged imitation, the Court stated that, under New Jersey law, its elements are, conjunctively, secondary meaning and nonfunctionality. A showing must be made that the allegedly nonfunctional element does not enhance efficacy. *Id.* (citing *William R. Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 526 (1924); *Norwich Pharmacal Co. v. Sterling Drug Inc.*, 271 F.2d. 569 (2d Cir. 1959), *cert. denied*, 362 U.S. 919 (1960). SK&F prevailed on this issue as well. The court noted that the adoption of trade dress for the DYAZIDE capsule was arbitrary, having nothing to do with the purpose or performance of the drug, or with its processing, and that its "only value was in identifying the goods with their source, and that value, suffices in the New Jersey courts to establish secondary meaning." As to functionality, the Court noted that an identical combination drug was marketed by a third party in a wholly different tablet form, and that there was ample evidence that neither the capsule form nor the color combination reflects any industry practice for the identification of diuretics. 625 F.2d. at 1064.

With respect to the plaintiff's claim under Section 43(a) of the Lanham Act, the Court held that "except for the interstate commerce requirement, the elements of unfair competition torts

prescribed by the New Jersey law and by Section 43(a) of the Lanham Act are the same." 625 F.2d. at 1066. Having found that SK&F had demonstrated a likelihood of success on these claims, it followed that success was likely under Section 43(a).

In the present case Par admittedly sought to make its product look like Merck's Indocin in form, color and size. This similarity is used as a selling point when Par promotes its product among pharmacists. The fact that one potential customer touted Par's product as an "Indocin generic look-alike" is significant. Jeffrey Levine, who oversees Par's sales and service department, testified on deposition that he believes that there are pharamacists who are inclined to substitute generic products illegally. His opinion that Par's label concerning unauthorized substitution for Indocin would deter those otherwise disposed towards illegal activity is unpersuasive. The motive, the opportunity and the inclination by some to substitute the generic drug illegally are all present when Par distributes its look-alike product. In these circumstances I conclude that Merck is likely to succeed on the merits on its New Jersey common law passing off claim.

Similarly, I conclude that Merck is likely to succeed on the merits on its New Jersey common law unprivileged imitation claim.

The evidence strongly supports Merck's position that the particular trade dress of its Indocin product (including its form, color combination, sizes and placement of its identifying letters) has acquired a secondary meaning denoting a common source of the product and denoting to doctors and pharmacists and at least to some patients that Merck was that source. The fact of Par's imitation of the trade dress is significant. By design the Par product is almost indistinguishable from Merck's. Even the designation PAR which is superimposed upon the Par product appears to all but the most observant person to be the same symbol as Merck's MDS which appears on the Indocin capsule. Extensive advertising, varied and substantial sales efforts and commercial success during a 14-year period are further indicia of secondary meaning.

Par urges strenuously that the trade dress serves a functional purpose and that therefore Merck has not established the second prong of its unprivileged imitation claim – non-functionality.

Most of the arguments which Par advances are the same as those urged unsuccessfully in *SK&F* and *Ciba-Geigy*. One is new. On the basis of information which Par developed during discovery, Par asserts that Merck did not select the blue color in an arbitrary and fanciful manner. Rather, on the basis of 1963 research, it determined that color, per se, has a therapeutic value. Reds produce responses which are stimulating and exciting; green produces responses which are calm, peaceful and serene; yellows induce cheerful, jovial and joyful responses; blues induce pleasant, secure, tender and soothing responses. Par argues that Merck selected blue for the response it would produce in patients. Thus, the color has a functional purpose. Apart from the fact that this alleged function served more in the nature of a promotional effect, Par did not simply select the blue color which it asserts has therapeutic qualities. It selected blue and white in the same pattern long used by Merck. There might well be no lawsuit if Par had chosen only the allegedly therapeutic blue color.

The other supposedly functional features of Merck's trade dress are those advanced in the other cases. The evidence in this case and the findings in other cases establish that when a prescription drug used by patients over an extended period of time, is sold in the same time trade dress for many years, the trade dress does, to some extent at least, make it easier for pharmacists and nurses to dispense drugs, provide a way for patients to avoid commingling drugs, and give the patient a feeling of continuity and security. I am not at all persuaded by the evidence that use of look-alike generic drugs materially assists a doctor in dealing with an emergency overdose situation.

I conclude that these advantages which have been established which are to be gained from using the same trade dress for generic drugs as was used for the previously patented drugs are

so minimal that they cannot serve to render the trade dress functional within the meaning of New Jersey law of unprivileged imitation.

Other drugs for use in other fields have the same blue and white color as Indocin. Antiarthritic drugs other than Indocin come in a wide range of colors and shapes. The four other generic indomethacin products which now compete with Indocin are produced in the colors green, pink and white, orange, and white. Any functional uses of the blue and white color scheme were not sufficiently substantial to preclude this competition from entering the market place.

These conclusions relating to the New Jersey common law lead to the further conclusion that Par's conduct also violates Section 43(a) of the Lanham act, 15 U.S.C. Section 1125(a) unless, as Par urges, the case of *Inwood Laboratories v. Ives Laboratories*, 456 U.S. 844 (1982) requires a different result. There in circumstances similar to the present case Ives (the manufacturer of the originally patented drug) instituted suit against Inwood, the manufacturer of a look-alike generic drug, under Section 32 and 43(a) of the Lanham Act. After a trial, the District Court found that Inwood's conduct did not violate Section 32 since Inwood had not suggested even by implication that pharmacists could dispense the generic drugs incorrectly as Ives' product.

Ruling on Ives' Section 43(a) claim, the District Court found that the color scheme which Inwood copied was functional for much the same reasons as Par urges in the present case. The District Court also found that Ives' color scheme did not indicate the drug's origin. The Court of Appeals for the Second Circuit concluded that Inwood had violated Section 32 and reversed without reaching Ives' Section 43(a) claim. Upon its review of the Second Circuit decision the Supreme Court reviewed the law concerning contributory infringement in violation of Section 32 and reversed because the Court of Appeals erred in setting aside findings of fact that were not clearly erroneous. The

opinion did not purport to rule on Ives' Section 43(a) claim. The Supreme Court's principal opinion concluded with the statement:

> Although the District Court also dismissed Ives' claims alleging that the petitioners violated Section 43(a) of the Lanham Act and the state unfair competition law, the Court of Appeals did not address those claims. Because Section 43(a) prohibits a broader range of practices than does Section 32, as may the state unfair competition law, the District Court's decision dismissing Ives' claims based upon those statutes must be independently reviewed. Therefore, we remand to the Court of Appeals for further proceedings consistent with this opinion.

456 U.S. at 858.

Thus, I do not believe that *Inwood v. Ives* constitutes a ruling on functionality under either Section 32 or Section 43(a) and that *SK&F* and *Ciba-Geigy* are still the law on this subject for 43(a) purposes.

It is likely that Merck will prevail on the merits both on its state law claim and on its Section 43(a) claim.

2. *Other Equitable Considerations:*

Turning to the other requirements for injunctive relief, Merck is threatened with irreparable injury. The likelihood of at least some illegal substitution poses a threat of liability for injuries for which Merck should not be responsible. It is threatened with direct monetary loss and injury to its reputation. These injuries often involve imponderables which cannot be translated into ascertainable monetary damages.

As far as Par's is concerned, there was no necessity for it to have adopted a trade dress which mimicked the dress utilized by Merck for more than 14 years. It could have adopted its own distinctive trade dress and built its own reputation as the other

manufacturers of the generic product had done. In behaving as it did it took a calculated risk and having lost it is eminently just that it bear the consequences.

Clearly the public has an interest in the production and sale of generic drugs at the lowest possible prices. But there are countervailing interests. One is in the unmistakable identification of the sources of drugs so that if there are defects in the product those who were responsible for the defects can be held responsible and so that those who are not responsible will not be threatened with undeserved suit. The public has an interest in drug manufacturers building and maintaining reputations for good quality products. The remedies provided under the Lanham Act are means to encourage the building and maintenance of such reputation.

Par urges on the basis of a Merck study that the generic products could obtain a greater share of the market if they could use the same trade dress as Indocin — that, in effect, it could compete more effectively. Judge Gibbons answered that argument, in *SK&F*, stating at page 1067:

> The only answer that Premo made when confronted with these factors was, in essence, that it could compete more effectively in the diuretic market if it could use the same maroon and white capsule color adopted by *SK&F* for DYAZIDE. Probably it could compete better still if it could appropriate the same trade name. But neither appropriation has the look, sound or feel of equity. Therefore, the trial court did not err in concluding that the competing equities favored preliminary injunction relief of *SK&F*.

The public has an interest in Par entering into competition in the manufacture and the sale of indomethacin, provided it does so on the strength of its own product sold under its own trade dress. The public does not have an interest in Par entering into such competition using a look-alike product which looks as if it came from another source.

All the conditions for the issuance of a preliminary injunction enjoining Par in the sale and distribution of indomethacin using the Indocin trade dress having been established, an injunction will issue. Merck's attorneys are requested to submit a form of order in accordance with this opinion.

APPENDIX E

ORDER OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY, *MERCK & CO., INC. v. PAR PHARMACEUTICAL, INC.*, NO. 84-1559 (D.N.J. September 26, 1984)

United States District Court

for the

District of New Jersey

Civil Action No. 84-1559

MERCK & CO., INC.,

Plaintiff,

vs.

PAR PHARMACEUTICAL, INC.,

Defendant.

ORDER

It is this 25th day of September 1984 *ORDERED* that the court's bench opinion in the above matter be corrected as follows:

1. At page 5, line 18 of the transcript the words "fifty percent" shall be changed to read "fifteen percent".

2. At page 13, line 3 and at page 17, line 4 of the transcript the words "fourteen-year" shall be changed to read "nineteen-year".

3. On page 5 at line 11 of the transcript the description of the capsules of Chelsea Laboratories, Inc. as "orange" shall be changed to "yellow for the 25 mg. capsules and blue for the 50 mg. capsules".

DICKINSON R. DEBEVOISE
U.S.D.J.

APPENDIX F

ORDER FOR PRELIMINARY AND FINAL INJUNCTION OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY, *MERCK & CO., INC. v. PAR PHARMACEUTICAL, INC.*, NO. 84-1559 (D.N.J. September 25, 1984)

United States District Court

for the

District of New Jersey

Honorable D. Debevoise

Civil Action No. 84-1559

MERCK & CO., INC.,

Plaintiff,

vs.

PAR PHARMACEUTICAL, INC.,

Defendant.

ORDER FOR PRELIMINARY AND FINAL INJUNCTION

This matter having been brought before the Court on the application of counsel for Merck & Co., Inc., plaintiff, for an Order of injunction *pendente lite* pursuant to Fed. R. Civ. Proc. 65; the Court having held a hearing on September 4, 1984 on plaintiff's motion for a preliminary injunction; the Court having considered the evidence and the argument of counsel and the papers submitted in connection therewith, and good cause having been shown.

IT IS ON THIS 25 day of September, 1984,

ORDERED that the motion of plaintiff, Merck & Co., Inc., for a preliminary injunction is hereby granted as follows:

1. Defendant, Par Pharmaceutical, Inc. and its officers, agents, servants, employees, affiliates and attorneys and all other persons in active concert or participation with them, or any of them, who receive actual notice of this Order by personal service or otherwise shall be and hereby are restrained and enjoined from directly or indirectly manufacturing, importing, selling, offering for sale, shipping, delivering, distributing or directing or causing or authorizing the manufacturing, importing, selling, offering for sale, shipping, delivering, or distribution of pharmaceutical products in or for use in the United States containing indomethacin in capsules bearing blue and white in combination as depicted in Exhibit A to the Affidavit of Douglas N. Durand sworn to June 14, 1984 and annexed hereto and/or representing or describing any indomethacin product of Par Pharmaceutical, Inc. which they or any of them manufacture, import, sell, offer for sale, ship, deliver or distribute as bearing the above described size, shape and color combination.

IT IS FURTHER ORDERED that all existing stocks of products containing indomethacin in blue and white capsules in the possession or under the control of Par Pharmaceutical, Inc., and its officers, servants, employees and affiliates who receive actual notice of this Order by personal service or otherwise shall be destroyed. This paragraph shall be stayed pending final disposition of any appeals; and

IT IS FURTHER ORDERED that delivery of a copy of this Order to the offices of defendant Par Pharmaceutical, Inc., 12 Industrial Drive, Saddle River, New Jersey or to defendant's counsel, Sheldon S. Lustigman, Esq., personally or to his offices at 158 Windham Road, Hillsdale, New Jersey 07642 by 5:00 p.m. on October 1, 1984 shall be deemed sufficient service of this Order upon said defendant.

IT IS FURTHER ORDERED that in accordance with the Final Judgment and Order of this date, this injunction is hereby made permanent.

ENTERED:

DICKINSON R. DEBEVOISE

U.S.D.J.

We hereby approve the form
of this Order.

SHANLEY & FISCHER, P.C.
Attorneys for Merck & Co., Inc.

By: _____
Ronald Gould

BASS & ULLMAN
Attorneys for Par Pharmaceutical, Inc.

By: _____
Lawrence H. Roth

_____
Sheldon S. Lustigman
Attorney for Par Pharmaceutical, Inc.

APPENDIX G

FINAL JUDGMENT AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY, *MERCK & CO., INC. v. PAR PHARMACEUTICAL, INC.*, NO. 84-1559 (D.N.J. September 25, 1984)

United States District Court
for the
District of New Jersey

Honorable Dickinson R. Debevoise

Civil Action No. 84-1559

MERCK & CO., INC.,

Plaintiff,

vs.

PAR PHARMACEUTICAL, INC.,

Defendant.

FINAL JUDGMENT AND ORDER

The Court having held a hearing in this action on September 4, 1984 on Plaintiff's motion for a preliminary injunction; the Court having considered the evidence and argument of counsel; the Court having made certain findings of fact and conclusions of law in an opinion dated September 5, 1984 granting plaintiff's motion for a preliminary injunction; the Court, upon request of defendant having consolidated the hearing held on plaintiff's motion for a preliminary injunction with the final trial on the merits pursuant to Fed. R. Civ. Proc. 65(a)(2); defendant having requested the Court to enter its decision as a final judgment rather than a preliminary injunction; and plaintiff having consented to the entry of final judgment,

IT IS ON THIS 25 day of September, 1984,

ORDERED that the findings of fact and conclusions of law set forth in the Court's Opinion of September 5, 1984 granting plaintiff's motion for a preliminary injunction shall be and hereby are adopted as the Court's findings of fact and conclusions of law which constitute the grounds for entry of final judgment and it is

FURTHER ORDERED that to the extent necessary any conclusion of law will be deemed a finding of fact and any finding of fact will be deemed a conclusion of law; and it is

FURTHER ORDERED, ADJUDGED AND DECREED:

A. That upon consideration of all the evidence and for the reasons set forth above and in the Court's Opinion of September 5, 1984, plaintiff has established its claims under the New Jersey state law of passing off and unprivileged imitation and under Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a);

B. That judgment is entered in favor of plaintiff and against defendant on the claims for relief set forth in the Complaint under Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a), New Jersey Statutes Annotated Section 56:4-1 and 56:8-2 and the common law of unfair competition of the State of New Jersey;

C. That the preliminary injunction issued on this day is made permanent;

D. Defendant's counterclaim and plaintiff's claim for an accounting shall be and hereby are dismissed with prejudice on the consent of the parties;

E. The parties by consent shall bear their own costs and attorneys fees to date.

DICKINSON R. DEBEVOISE

DICKINSON R. DEBEVOISE,
U.S.D.J.

We hereby approve the form of this Order.

SHANLEY & FISCHER, P.C.
Attorneys for Merck & Co., Inc.

By _____
Ronald Gould

BASS & ULLMAN
Attorneys for Par Pharmaceutical, Inc.

By _____
Lawrence H. Roth

_____
Sheldon S. Lustigman
Attorney for Par Pharmaceutical, Inc.

APPENDIX H

ARTICLE I, SECTION 8, CLAUSE 8 OF THE CONSTITUTION OF THE UNITED STATES

The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries;

ARTICLE VI, PARAGRAPH 2 OF THE CONSTITUTION OF THE UNITED STATES

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

§43(a) OF THE LANHAM ACT, 15 U.S.C. §1125(a)

§1125. False designations of origin and false descriptions forbidden

(a) Any person who shall affix, apply, or annex, or use in connection with any goods or services, or any container or containers for goods, a false designation of origin, or any false description or representation, including words or other symbols tending falsely to describe or represent the same, and shall cause such goods or services to enter into commerce, and any person who shall with knowledge of the falsity of such designation or origin or description or representation cause or procure the same to be transported or used in commerce or deliver the same to any carrier to be transported or used, shall be liable to a civil action by any person doing business in the locality falsely indicated as that of origin or in the region in which said locality is situated, or by any perosn who believes that he is or likely to be damaged by the use of any such false description or representation.

NEW JERSEY STATUTES ANNOTATED SECTION 56:4-1

56:4-1. Appropriation of name, brand, trade-mark, reputation or goodwill of maker by dealer in product of maker

No merchant, firm or corporation shall appropriate for his or their own use a name, brand, trade-mark, reputation or goodwill of any maker in whose product such merchant, firm or corporation deals.

NEW JERSEY STATUTES ANNOTATED SECTION 56:8-2

56:8-2 Fraud, etc., in connection with sale or advertisement of merchandise or real estate as unlawful practice

The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice; provided, however, that nothing herein contained shall apply to the owner or publisher of newspapers, magazines, publications or printed matter wherein such advertisement appears, or to the owner or operator of a radio or television station which disseminates such advertisement when the owner, publisher, or operator has no knowledge of the intent, design or purpose of the advertiser.